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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,854	07/23/2003	Andre Delacourte	11362.0039.NPUS01	9442

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EXAMINER	
WANG, CHANG YU	
ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 11/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/625,854	DELACOURTE ET AL.	
	Examiner	Art Unit	
	Chang-Yu Wang	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *April 21, 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26 and 29-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *26 and 29-54* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 26 and 29-43 (in part), drawn to a method for determining the susceptibility to a disease associated with β-amyloid formation/aggregation, classified in for example class 435, subclass 7.21.

II. Claims 26 and 29-43 (in part), drawn to a method for screening of the clearance of β-amyloid deposition in a mammal, classified in for example class 435, subclass 7.21.

III. Claims 44-49, 52 and 54, drawn to a diagnostic/theranostic kit, classified in for example class 424, subclass 130.1.

IV. Claims 50, 51 and 53, drawn to a method for the preparation of an antibody, classified in for example class 435, subclass 69.1.

2. The inventions are distinct, each from the other because of the following reasons:

3. Inventions I and II are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the inventions I can have a materially different design, mode of operation, function and effects. The method for determining the susceptibility to or the risk of developing a disease

associated with β-amyloid formation in the Group I can be substituted by detecting the mutation of the molecules involved in the process of β-amyloid formation using short tandem repeat primers to determine the linkage with certain gene loci or using antibodies against to the molecules involved in the process of β-amyloid. The method for screening of the clearance of β-amyloid deposition in the Group II can be used the antibody recognizing the β-amyloid or any molecules with the capability of binding to β-amyloid. Thus, Inventions I and II are patentably distinct.

4. Inventions I-II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process for using the product as claimed can be practiced with another materially different product. First, the pathogenesis of a disease associated β-amyloid formation can be due to the gene mutation in the molecules involved in the process of amyloid formation. Therefore, the method for determining the susceptibility to or the risk of developing a disease associated with β-amyloid formation can be substituted by detecting the gene mutation of molecules involved in the process of β-amyloid formation using short tandem repeat primers to determine the linkage with certain gene loci. It can also be substituted by

detecting other molecules such as presenilin or γ-secretase. Thus, Inventions I and II are patentably distinct.

5. Inventions III and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process as claimed can be used to make other and materially different product. The method of preparing an antibody claimed in the Group IV can be used to prepare other antibodies. Therefore, Inventions III and IV are patentably distinct.

6. Inventions I-II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In this instant case, first, the materials, steps and outcomes for the method of determining the susceptibility to a disease or screening the clearance of amyloid are very different from those of preparing an antibody. Second, the method of preparing an antibody does not require the steps or materials in the method of determining the susceptibility to a disease of β-amyloid formation. Therefore, the Inventions I-II and IV are patentably distinct.

7. Furthermore, in addition to the election of one of the above IV groups, further restriction is required under 35 U.S.C. 121 as set forth below to delineate the molecular embodiments to which the claims will be restricted in accordance with the elected group:

A. A single designated molecule selected from A) N-terminal truncated/ post-translationally modified β-amyloid variant, B) N-terminal APP soluble fragment, C) C-terminal fragment, D) antibody specific for β-amyloid variant or E) antibody specific for APP soluble fragment needs to be elected if one of the Groups I-IV is elected.

B. A single designated molecule selected from A) peptide, B) antibody, or C) nucleic acid as recited in claims 30, 50 and 51, if one of the Groups I-II and IV is elected.

8. The inventions are distinct, each from the other because of the following reasons:

9. Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because the products indicated as groups A-B constitute patentably distinct inventions for the following reasons. Each of the polypeptides has a unique structural feature which requires a unique search of the prior art. The inventions indicated in the groups A-B differ in structure and function as they are composed of divergent amino acids, nucleic acids, and antibodies, and thus the use for each molecule is different. The different polypeptides are processed differently with

different molecular mechanisms. In addition, the neurotoxicity and antigenicity of these different polypeptides are different. Accordingly, the effects/outcomes of these different polypeptides are distinct. Further, since the polypeptides are different, the antibodies generated from these different peptides can recognize differentially. Consequently, the use of these antibodies is different in therapeutical or biotechnical purposes. Therefore, groups A-B constitute very divergent subject matters. A reference to one element would not constitute a reference to another. In addition, searching all of the molecules and neurological conditions in a single patent application would provide an undue search burden on the examiner and the USPTO's resources because the indicated searches are not co-extensive.

10. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

11. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). In order to be fully responsive, Applicant is required to elect a single group from designated Groups I-IV and a single molecular embodiment from designated groups A-B to which the claims will be restricted, even though the requirement is traversed. Applicant is advised that none of the Groups I-IV and A-B are species election requirements; rather each of the Groups I-IV and A-B are restriction requirements. The subject matter for examination will be restricted to the extent of the

subject matter of the elected groups. It is noted that while groups A-B may not be applicable to one of Groups I-IV, applicant must elect one of each in order to be fully compliant.

Election of Species

12. This application contains claims directed to the following patentably distinct species of the claimed inventions I-IV:

i. The species of the start position of the N-terminal truncated β-amyloid variant as stated in the Groups I-IV are as follows:

A) 2, B) 3, C) 4, D) 5, E) 6, F) 7, G) 8, H) 9, or I) 10 of β-amyloid.

ii. The species of the post-translationally modification for β-amyloid as stated in the Groups I-II are as follows:

A)-D) methylation at positon 1, 2, 4, 6, or E) pyroglutamylation at position 3 of β-amyloid.

iii. The species of the determined molecule for the susceptibility to Alzheimer's disease as stated in the Group I-III are as follows:

A) Aβ (5-42) or B) Aβ (8-42).

13. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

14. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

15. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

16. The claims are deemed to correspond to the species listed above in the following manner:

If one of the Groups I-IV is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of the start position of the N-terminal truncated β-amyloid variant from groups i-iii for prosecution on the merits

to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 26, 44, 50 and 53 are generic.

If one of the Groups I-II is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for post-translationally modification from group ii for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 26 is generic.

If one of the Group I-III is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for the determined molecule for the susceptibility to Alzheimer's disease for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 26 and 44 are generic.

17. The species listed above are patentably distinct for the following reasons:

These species are distinct because they are different peptides. Each specific species differs with respect to its composition, structural feature, function and use. The different peptides are processed differently with different molecular mechanisms. In addition, the degree of the neurotoxicity and antigenicity for these different peptides is different. Consequently, the effects/outcomes of using these different polypeptides are distinct. Further, since the peptides are different, the antibodies raised against to these different peptides can differently binds to different epitopes. Accordingly, the use of

these antibodies is different in therapeutical or biotechnical purposes. Thus, these species are patently distinct.

18. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). In order to be fully responsive, Applicant is required to elect a single group from designated Groups I-IV, a single designated molecule from groups A-B and a single species from groups i-iii that are applicable as set forth above to which the claims will be restricted, even though the requirement is traversed. The subject matter for examination will be restricted to the extent of the subject matter of the elected groups and species.

19. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

20. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

21. Papers relating to this application may be submitted to Technology Center 1600, Group 1649 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (571) 273-8300.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang, Ph.D. whose telephone number is (571) 272-4521. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, Ph.D., can be reached at (571) 272-0867.

23. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CYW
October 31, 2005

SUPERVISORY PATENT EXAMINER